Mycenax Biotech Inc.
永昕生物醫藥股份有限公司

2016年8月25日

免責聲明

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公司基本資料

產業別	生物藥品開發
實收資本	新台幣11.13億元
主要法人股東	晟德大藥廠(股)公司(10.19%)、年興紡織(股)公司(7.42%)、上智生技創業投資(股)公司(4.61%)、行政院國發基金(3.99%)
成立時間	2001年9月28日
公司地址	苗栗縣竹南鎮科東三路8號2樓
員工人數	123人 (RD & GMP 105人)
主要業務	生物藥品開發 生物藥品委託開發服務

簡報大綱

- 永昕的願景、策略與發展歷程
- 生物藥品的特性
- 永昕的營運進展
  - TuNEX
  - LusiNEX
  - Bionovel

願景Vision

讓研究成果商品化，改善人類生命品質
From Bench to Better Life

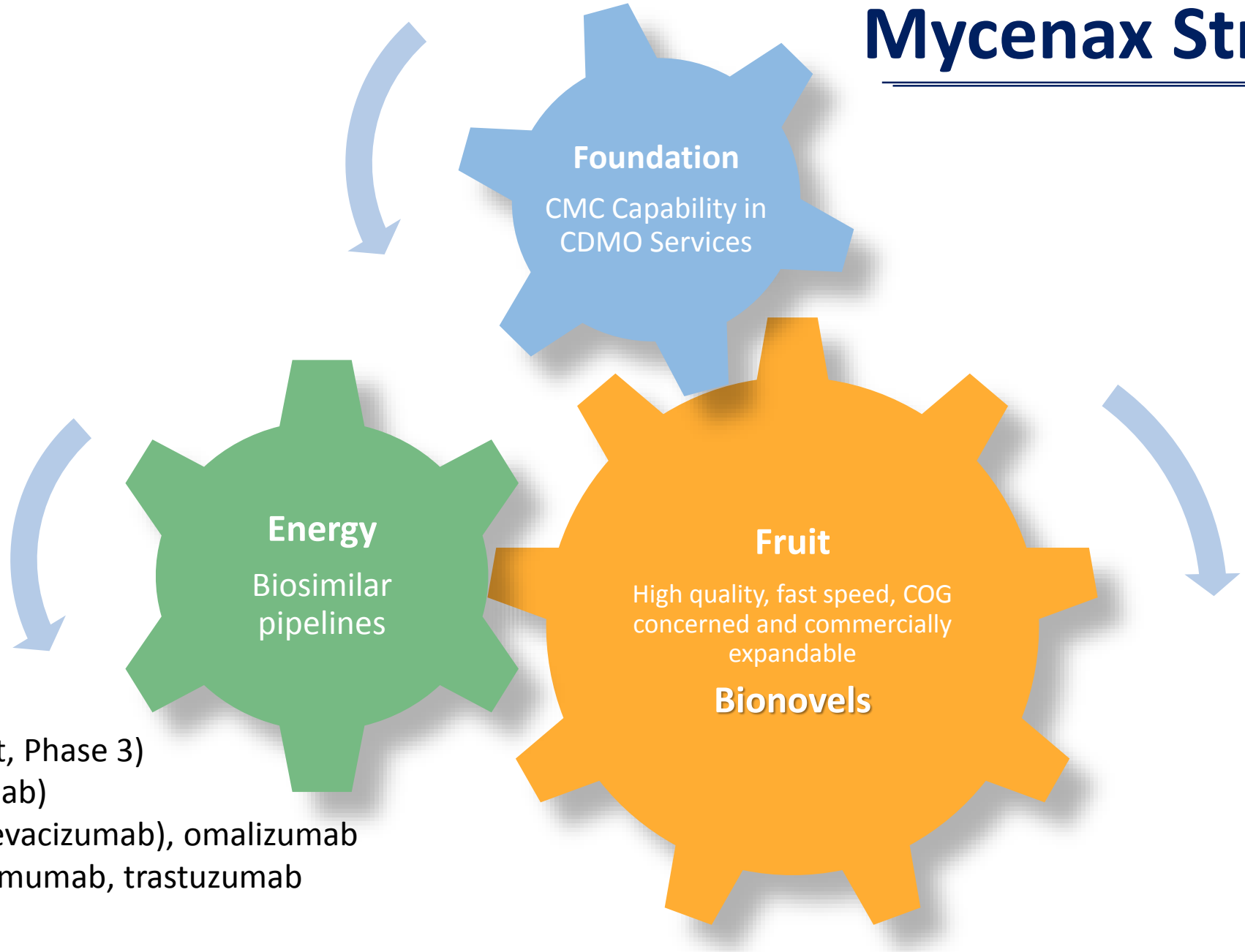
使命 Mission

專精於品質與成本兼顧的基因工程藥品平台開發
Specializing in developing quality and cost competitive platforms for recombinant biological drug through biosimilar product launch to the market and CDMO business

致力於生物藥品之自我或共同開發
Focusing on developing biologics through self development or co-development with global partner

成為基因工程之生物新藥開發公司
Becoming a biopharmaceutical company with complete product development value chain and strong partnership with local market.

Mycenax Strategy



- TuNEX (etanercept, Phase 3)
- LusiNEX (tocilizumab)
- Co-dev.: AiNEX (bevacizumab), omalizumab
- Clone ready: adalimumab, trastuzumab

公司發展歷程

2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
◆公司成立			◆引進TuNEX 細胞株，開始開發 ◆國內第一家使用**拋棄式製程**的生物藥廠	◆FDA DMF Type V 註冊，註冊編號：17981	◆廠房取得cGMP 認證(API)		◆廠房取得cGMP 認證(DP) ◆TuNEX Phase I IND (KR) ◆TuNEX Phase I/II IND (TW)	◆TuNEX Phase I/II 完成 ◆TuNEX Phase I/PK 完成，Phase III IND 核可(KR)	◆TuNEX Phase III IND (TW)	◆建置200/500 L SUB	◆建置2,000L SUB 產線 ◆廠房取得PIC/S GMP 認證 ◆股票於櫃買中心上櫃掛牌交易，股票代碼4726)	◆啟動LusiNEX 開發計畫	◆TuNEX Phase III (TW) 完成180 人受試者收案	◆TuNEX Phase III (TW) 解盲	◆建置50L turbo (microbial) 產線

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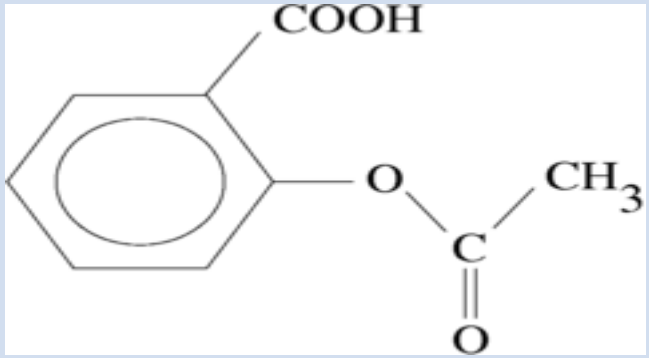
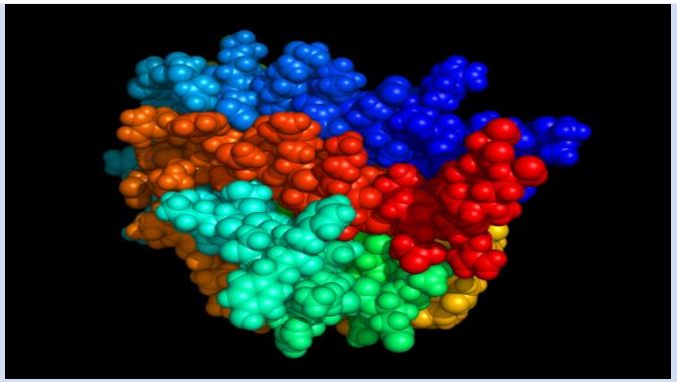
Size and Complexity Comparison

Chemical Entity	Biological Entity- Protein	Biological Entity- mAb
		
Ex. Aspirin	Ex. Epogen	Ex. Rituxan
21 atoms MW <500	~3,000 atoms 165 amino acids MW:30 KD Glycosylation involved in activity	~25,000 atoms 415 amino acids of 2 heavy chains+213 amino acids of 2 light chains. MW: 145 KD Glycosylation involved in activity
		

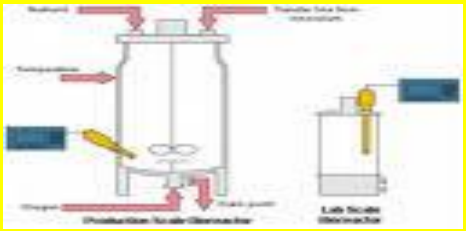
Mycenax

生物藥的開發流程

Drug Discovery

+

Cell Line Development



Process Development

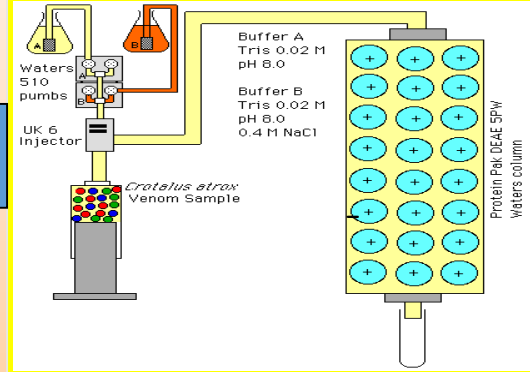
Bioanalysis/ CMC

GLP Toxicology

Efficacy/ PD/PK

IND

Phase I & II Clinical Trials



Large Scale GMP Production

Phase III Clinical Trial

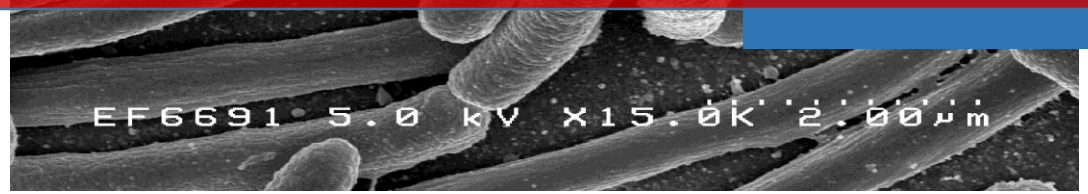
Approval

Process is the Product製程即產品

宿主 + 養分、環境 + 宿主貢獻之結構後修飾

➡ 不同的特性之蛋白質/單株抗體

蛋白藥/抗體藥因無法擁有不同來源之API
具不可取代性
藥品掌握的關鍵:
產程開發
CMC(藥品化學、製造與管制)



Bioanalysis/
CMC

Comparison of New Drug, Generics and Biosimilars

Category	New Drug-chemicals	Generics	New Drug- biologics	Biosimilar (EMA)	Biosimilar (TW)
CMC	Full CMC dossier	Full CMC dossier (complied to spec.)	Full CMC dossier	Full CMC dossier	Full CMC dossier
	-	-	-	Comparison study ➢ Protein Characterization ➢ Stress test	Comparison study ➢ Protein Characterization ➢ Stress test
	Scale/GMP α clinical stage advanced. NDA scale can be 1/10 of the commercial batch	NDA scale cane be 1/10 of the commercial batch	Scale/GMP α clinical stage advanced. Phase III scale= NDA scale = commercial scale	IND and commercial batch size: same If not, **COMPARABIILITY** is required.	IND and commercial batch size: same If not, **COMPARABIILITY** is required.
Non-clinical	Pharmacodynamic	-	Pharmacodynamic	Comparison PD	Comparison PD
	Pharmacokinetic	-	Pharmacokinetic	Comparison Pk	Comparison Pk
	Safety pharmacology	-	Safety pharmacology	-	-
	Single dose toxicity	-	Single dose toxicity	-	-
	Repeated dose toxicity ➢Immunogenicity ➢TK ➢Local tolerance	-	Repeated dose toxicity ➢Immunogenicity ➢TK ➢Local tolerance	Comparison repeated tox, if request ➢Immunogenicity ➢TK ➢Local tolerance	Comparison repeated tox, if request ➢Immunogenicity ➢TK ➢Local tolerance
	Carcinogenicity	-	-		
	Reproduction toxicity	-	Reproduction toxicity	-	-
Clinical	-	Comparative PK studies (BE)	-	Comparative PK studies	Comparative PK studies
	Phase I trial	-	Phase I trial	-	-
	Phase II trial	-	Phase II trial	-	-
	Two pivotal trial (Placebo control)	-	**Two pivotal trial (Placebo control)**	**Comparison efficacy/ safety trial**	**Pivotal trial (Placebo control) for tentative approval** **Comparison efficacy/ safety trial in phase IV**

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TuNEX® (etanercept; Enbrel®-similar)

Process and analytical methods development in Mycenax Manufacturing on Mycenax's PIC/S GMP Biomanufacturing Facility, from cell banking to aseptic/fill	
CMC	● CTD module 3 ready ● Highly similar with extensive comparability with reference medicinal product (RMP)
Non-clinical studies	● CTD module 4 ready ● Full package of nonclinical studies
Clinical studies	● Phase I PK (TuNEX® vs. RMP): completed and result showed no significant difference. It was conducted in Korea ● Phase I/II (TuNEX®): completed and result showed safe with efficacy. It was conducted in Taiwan ● Phase III: two trials on-going with patients enrollment completed. The trials will be completed in Q1 2016. ● Market approval by TFDA (by early 2017)
NDA submission	● Reviewed by CDE ● Marketing approval expected in early 2017.

- Study II 臨床試驗數據於三月底解盲
- Study I 臨床試驗數據於六月底解盲
- **5/5已正式申請藥品查驗登記(NDA)**
- **6月底即取得TFDA第一次意見回覆，拼年底取證**

Further progress

- 海外擴張
- 液體劑型

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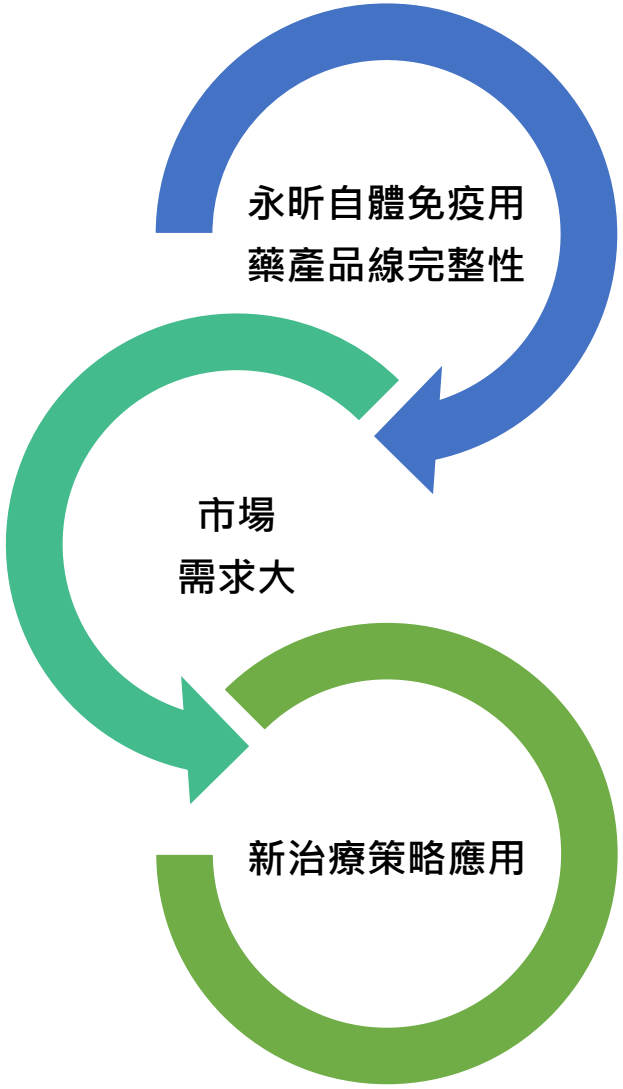
LusiNEX 開發: 完善永昕AIR疾病用藥！

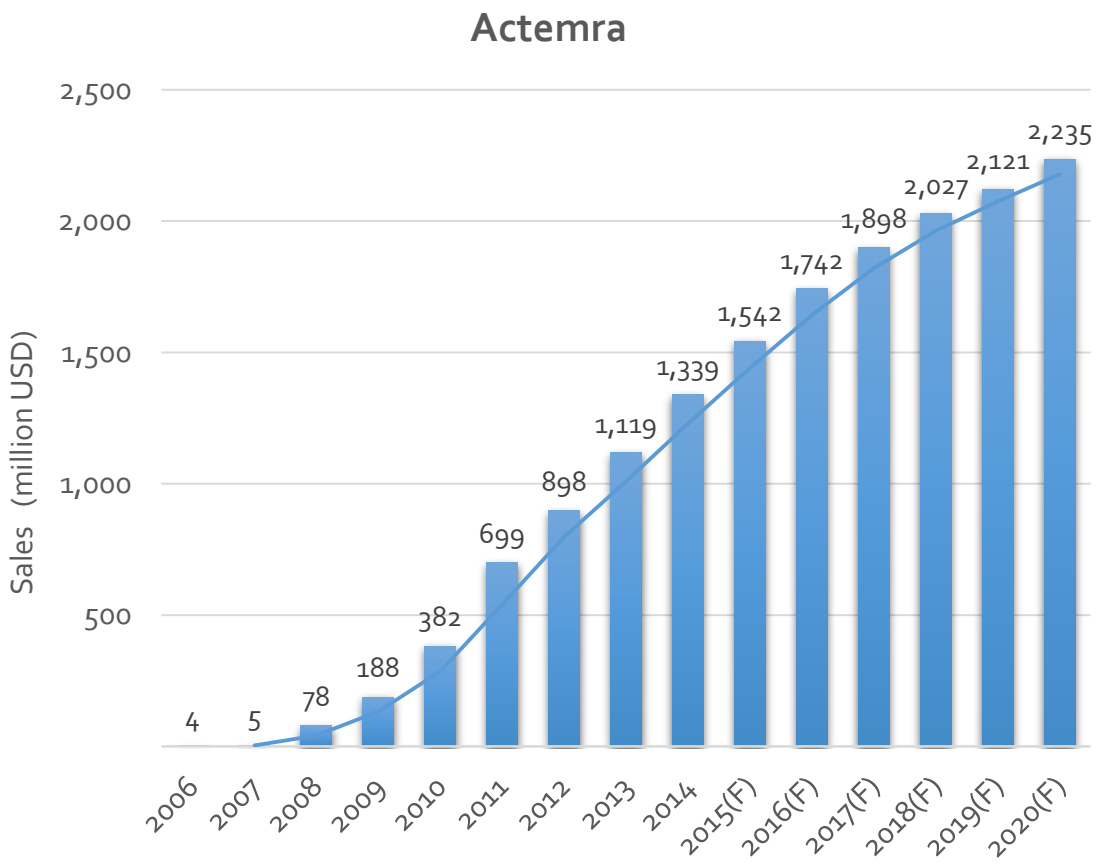


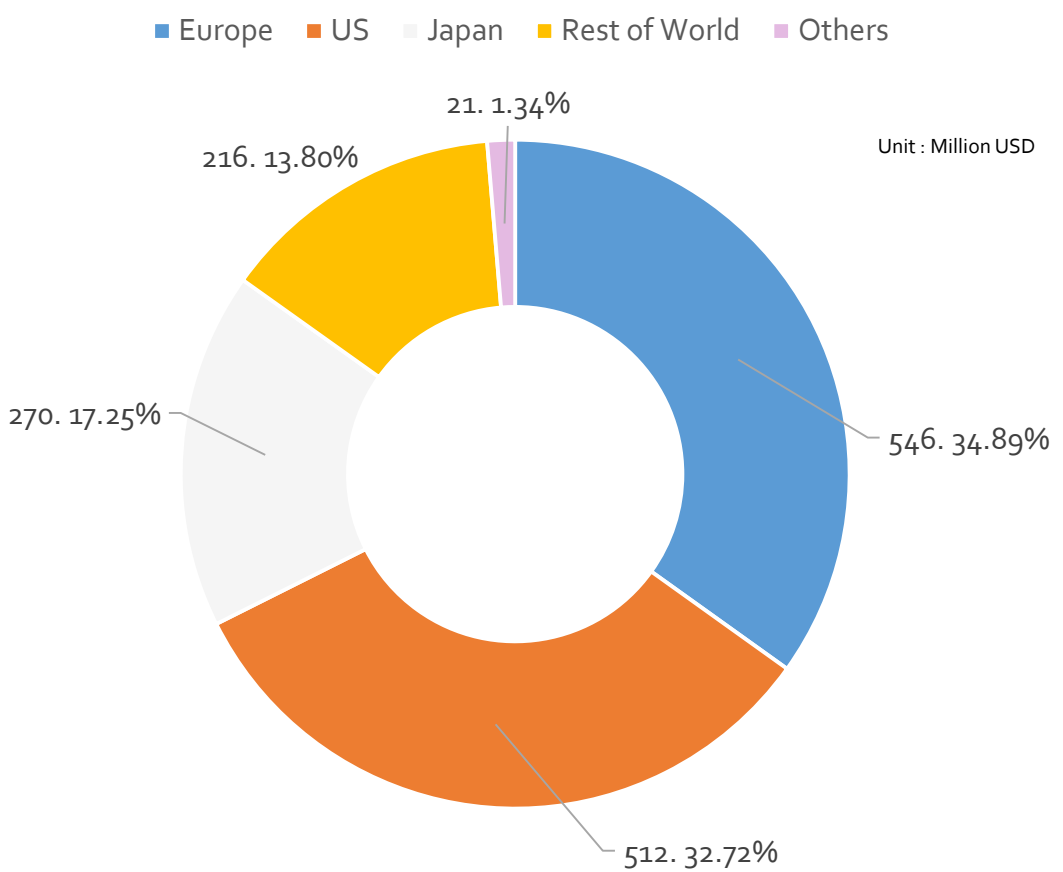
- TuNEX (TNFα antagonist)
- IL-6R antagonist (非TNF-α inhibitor)
- 創造永昕治療領域藥品開發品牌效應

- 自體免疫類疾病市場成長率快，生物相似藥進入市場之接受度挑戰較新藥低

- 協同TuNEX ，完整對於不同病程之患者治療
- Actemra在療效上有超越TNF-a inhibitors的趨勢(嚴重RA可不須經過MTX fail)
- 抗癌藥、其它自體免疫疾病適應症 (castleman disease、systemic sclerosis)

Global Market Potential - Tocilizumab





Source :

1. Roche Global Factsheet
2. GlobalData

LusiNEX® (tocilizumab; Actemra® and Roactemra®-similar)

Process and analytical methods development in Mycenax Manufacturing on Mycenax's PIC/S GMP Biomanufacturing Facility, from cell banking to aseptic/fill.	
Pre-IND	● Titer ~ 4g/L ● Highly similarity demonstrated by comparing the small scale product with multiple lots of reference medicinal products (RMPs) ● 2000L scale process development completed. ● 3 consecutive runs of cGMP . ● Extensive comparability in large scale products with multiple lots of RMPs
IND submission	● EMA consultation in 2016. ● EU IND submitted in Q2 2017.
Clinical studies design	● Pharmacokinetic study: LusiNEX® vs. RMP ● Pivotal (safety and efficacy study): LusiNEX® vs. RMP.

Competitive Analysis – Tocilizumab-Biosimilar

Brand Name	Company	Partner	Cell Clone	Pre-clinical	Phase I	Phase II	Phase III	Market
LusiNEX	**Mycenax Biotech Inc. (TW)**	n.a			IND filing in 2017Q2			
BOW-070 LZM 008	**Epirus Biopharmaceuticals, Inc. (US)**	Livzon Mabpharm, Inc. (CN)[1] Polpharma Group (PL)[2]						
ONS-3030[4,5]	**Oncobiologics, Inc. (US)**	n.a						
n.a[5]	**BioXPRESS Therapeutics SA (CH)**	n.a						
n.a[5]	**PanPharmaceuticals USA Inc. (US)**	n.a						

Note :

1. China. Sep.25, 2014
2. EU (w/o Austria, Belgium, Denmark, Finland, Luxembourg, the Netherlands, Sweden, Switzerland, Norway), Middle East, Turkey Russia and CIS territories
3. Source : GlobalData
4. http://www.biospace.com/News/oncobiologics-pushes-into-biosimilars-market-with/375184
5. http://adisinsight.springer.com/

LusiNEX® MHRA諮詢取得正向回覆

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Mr Gill
Clinical Network Services (UK) Ltd on behalf of
Mycenax Biotech Inc.
Fountain Court
2 Victoria Square
St Albans AL1 3TF

151 Buckingham Palace Road
Victoria
London SW1W 9SZ
United Kingdom

Telephone
+44 (0) 20 3080 6000
www.mhra.gov.uk

Date 4th August 2016

Ref: 1311/LusiNEX

Dear Mr Gill

On the 4th of July 2016 you met with staff from the MHRA:

Dr Julian Bonnerjea - Unit Manager
Dr Leonard Both - Quality Assessor
Dr Adrian Thomas - Quality Assessor
Dr Andrea Wallington - Medical Assessor
Dr Kristina Ulrich - Non-clinical Assessor
Dr David Wright - Statistical assessor

to discuss quality, non-clinical and clinical aspects of LusiNEX (tocilizumab) as a biosimilar to RoActemra.

ycenax 昕生物醫藥

LusiNEX® MHRA諮詢取得正向回覆

- CMC:
  - QTPP accepted
  - Specification on DS specification and DP specification: accepted
  - Similarity in small scale: accepted and should be applied to large scale, 2000L, the commercial scale.
- Nonclinical studies design: agreed
- Clinical studies design for phase 1 and phase 3: agreed.

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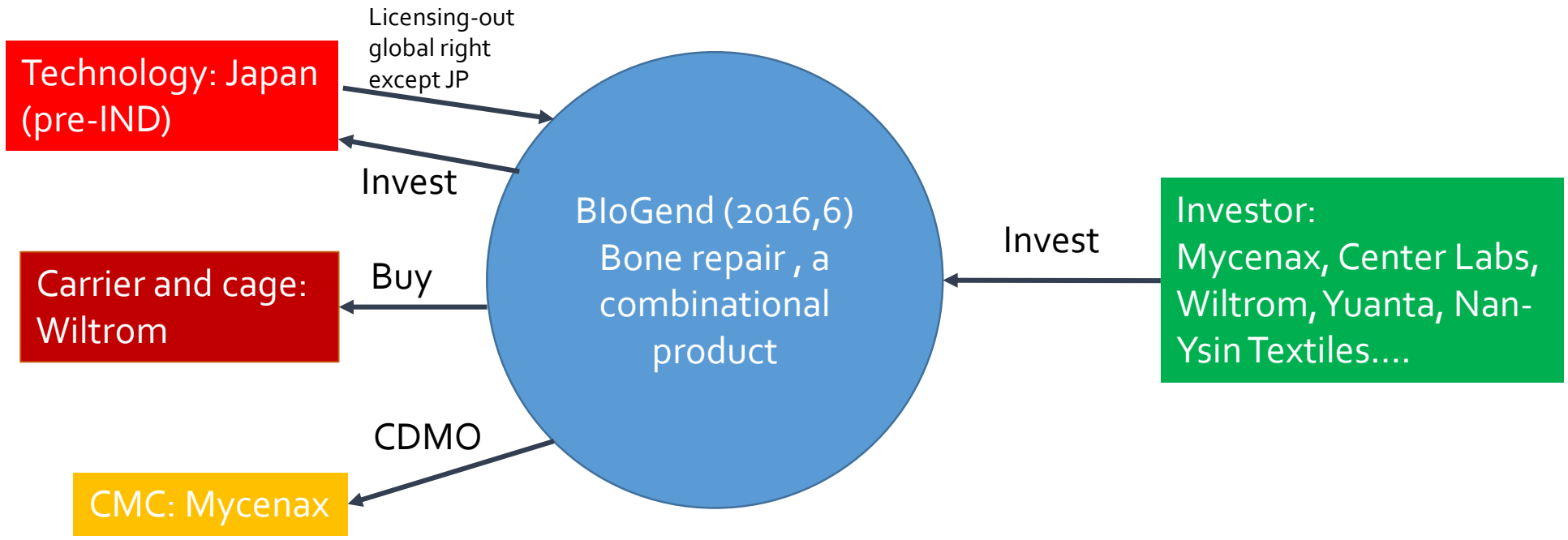
1st invested co-development project



Thanks for Your Attention

From Bench to Better Life

Karen Wen: klwen@mycenax.com.tw

Mycenax Biotech Inc.
永昕生物醫藥股份有限公司